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AUG 10 2006

510(k) Summary
Knee Fusion Nail

Submitter's Name:	Smith & Nephew, Inc., Orthopaedics
Submitter's Address:	1450 Brooks Road, Memphis, TN 38116
Submitter's Telephone Number:	901-399-6670
Contact Person:	John Reabe
Date Summary Prepared:	June 22, 2006
Trade or Proprietary Device Name:	Knee Fusion Nail
Common or Usual Name:	Intramedullary Nail
Classification Name:	Intramedullary fixation rod 21 CFR 888.3020
Device Class:	Class II
Panel Code:	Orthopaedics/87/JDS

Device Description

The Knee Fusion Nail is inserted in the medullary canal of long bones for knee arthrodesis. The Knee Fusion Nail features holes/slots on both ends of the nail for optional locking screws. The nails and screws are made of Stainless Steel. The screws were previously cleared in 510(k) K983942.

Intended Use

The Knee Fusion Nail is intended for intramedullary knee arthrodesis.

Device Comparison to Legally Marketed Devices

The Knee Fusion Nail is substantially equivalent to the Smith & Nephew Knee Fusion Nail included in 510(k) K050938 based on intended use and design features. The subject nail is Stainless Steel, similar to predicate nails in 510(k)s K893377 and K983942.

The Knee Fusion Nail is substantially equivalent to the Smith & Nephew Intramedullary Knee Fusion Nails included in 510(k)s K893377 and K983942 based on intended use and material.

The Knee Fusion Nail is substantially equivalent to the Smith & Nephew Titanium Nails included in 510(k) K981529 based on design features such as screw hole/slot configuration. The predicate nails are made of Titanium, available in shorter lengths and not intended for knee arthrodesis.

Performance Testing

The Knee Fusion Nail was compared to predicate Intramedullary Knee Fusion Nails through an analysis of bending strength and flexural rigidity based on the cross-sectional geometry of the nail's shaft region and the material strength properties using hand calculations. The yield strength, ultimate bending strength and flexural rigidity of the subject Knee Fusion Nail were shown to be equivalent or superior to the predicate Knee Fusion Nails included in 510(k)s K893377 and K983942.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 10 2006

Smith & Nephew, Inc.
% Mr. John Reabe
Director Regulatory Affairs
Orthopaedics Division
1450 Brooks Road
Memphis, Tennessee 38116

Re: K061783
Trade/Device Name: Knee Fusion Nail
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: JDS
Dated: June 23, 2006
Received: June 26, 2006

Dear Mr. Reabe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

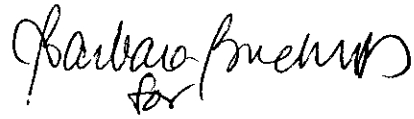
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K061783

Device Name: Knee Fusion Nail

Indications for Use:

Knee Fusion Nails are intended for intramedullary knee arthrodesis.

Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061783